

WHAT IS CLAIMED IS:

1                   1.       A handheld ultrasound device weighing less than fifteen pounds,  
2 including a transducer, beamformer and image processor and a first digital signal processor  
3 capable of processing B mode and flow (2D Doppler) scans, having an second digital  
4 processor block comprising:

5                   a digital Doppler QBP filter (FPGA) for filtering PW Doppler signals; and  
6                   a second digital signal processor core for PW Doppler signal processing.

1                   2.       The handheld ultrasound device of claim 1, more preferably weighing  
2 less than ten pounds.

1                   3.       The handheld ultrasound device of claim 1, even more preferably  
2 weighing less than seven pounds.

1                   4.       The handheld ultrasound instrument of claim 1, wherein the first  
2 digital signal processor, the second digital signal processor and the FPGA are unified onto a  
3 single application specific integrated circuit (ASIC) chip.

1                   5.       The handheld ultrasound device as described in claim 1, wherein the  
2 beamformer, image processor, first and second digital signal processors and FPGA are  
3 integrated into a single ASIC chip.

1                   6.       The handheld ultrasound device of claim 1, wherein the second digital  
2 signal processor for performing M mode interpolation, digital Doppler QBP filtering and PW  
3 Doppler signal processing are located on a digital signal processing application specific  
4 integrated circuit (ASIC) chip.

1                   7.       The handheld ultrasound device of claim 1, further comprising a time-  
2 motion display capability (M mode) wherein the M mode signal processing occurs on the first  
3 digital signal processor using a micro-code block, and interpolation of M-mode signal for  
4 video display is done on the second digital signal processor.

1                   8.       The handheld ultrasound device of claim 1, further comprising a means  
2 for performing tissue harmonic imaging.

1 9. The handheld ultrasound device of claim 1, further comprising a serial  
2 I/O port for sending and receiving data to peripheral devices.

1 10. The handheld ultrasound device of claim 1, further comprising a CW  
2 Doppler circuit having a CW beamformer ASIC and a supplemental circuit for A/D filtering  
3 and performing analog to digital conversion on I and Q signal pairs, wherein the FPGA of the  
4 second digital processor block processes complex data at a constant sample rate prior to  
5 processing through the second digital signal processor core.

1 11. The handheld ultrasound device of claim 10, having circuitry for  
2 performing transmit and receive signal control combined with a CW beamformer on a single  
3 ASIC chip, and having I/O ports for access to other process circuitry (2D, M mode, B mode).

1 12. An ultrasound diagnostic instrument comprising:.

2 a) a handheld module including a display, manual controls, and system  
3 circuitry for processing signals for display;

4 b) a transducer assembly coupled to the system circuitry for providing  
5 electrical signals from ultrasound waves for processing; and

6 c) an electrocardiograph (ECG) module coupled to the handheld module  
7 by a cable and including leads for receiving ECG signals from a patient and ECG signal  
8 processing circuitry for applying ECG signals to the handheld module through the cable.

1 13. The ultrasound diagnostic instrument as defined by claim 12, wherein  
2 the ECG module receives control and power signals from the handheld module.

1 14. The ultrasound diagnostic instrument as defined by claim 12, wherein  
2 the signal processing circuitry of the ECG module includes first amplification and filtering  
3 circuitry for signals from the leads and second amplification and filtering circuitry for  
4 processing signals from the first amplification and filtering circuitry for application to the  
5 handheld module, the first and second amplification and filtering circuitry being electrically  
6 isolated whereby a patient is electrically isolated from the handheld unit.

1 15. The ultrasound diagnostic instrument as defined by claim 14, wherein  
2 the first amplification and filtering circuit receives electrical power from the handheld

3 module, the electrical power being capacitively coupled to the first amplification and filtering  
4 circuitry.

1 16. The ultrasound diagnostic instrument of claim 15, wherein the  
2 transducer assembly is coupled to the system circuitry through a cable.

1 17. The ultrasound diagnostic instrument as defined by claim 15, wherein  
2 the transducer assembly is integral with the handheld module.

1 18. The ultrasound diagnostic instrument as defined by claim 12, wherein  
2 the signal processing circuitry of the ECG module includes first amplification and filtering  
3 circuitry for signals from the leads and second amplification and filtering circuitry for  
4 processing signals from the first amplification and filtering circuitry for application to the  
5 handheld module, the first and second amplification and filtering circuitry being optically  
6 coupled.

1 19. The ultrasound instrument as defined by claim 18, wherein the first and  
2 second amplification and filtering circuitry are being magnetically coupled.

1 20. The ultrasound instrument as defined by claim 18, wherein the  
2 first and second amplification and filtering circuitry are being capacitively coupled.

1 21. The ultrasound diagnostic instrument as defined by claim 12, wherein  
2 the transducer assembly is coupled to the system circuitry through a cable.

1 22. The ultrasound diagnostic instrument as defined by claim 12, wherein  
2 the transducer assembly is integral with the handheld module.

1 23. The ultrasound diagnostic instrument as described in claim 12, wherein  
2 said hand held module further comprises circuitry for performing spectral Doppler analysis  
3 and allowing for simultaneous ECG readings to be overlaid on a spectral Doppler display.

1 24. For use with a handheld ultrasound diagnostic instrument, an  
2 electrocardiograph (ECG) module comprising:  
3 leads for receiving ECG signals from a patient;  
4 ECG signal processing circuitry; and

5 a cable for applying ECG signals from the ECG signal processing circuitry to  
6 the handheld module.

1 25. The ECG module as described in claim 24, wherein the ECG module  
2 receives control, clock and power signals from the handheld ultrasound diagnostic  
3 instrument.

1 26. The ECG module as defined by claim 25, wherein the signal  
2 processing circuitry of the ECG module includes first amplification and filtering circuitry for  
3 signals from the leads and second signal amplification and filtering circuitry for processing  
4 signals from the first amplification and filtering circuitry for application to the handheld  
5 ultrasound diagnostic instrument, the first and second amplification and filtering circuitry  
6 being optically coupled.

1 27. The ultrasound instrument as defined by claim 26, wherein the first and  
2 second amplification and filtering circuitry are being magnetically coupled.

1 28. The ultrasound instrument as defined by claim 26, wherein the first and  
2 second amplification and filtering circuitry are being capacitively coupled.

1 29. The ECG module as defined by claim 26, wherein the first  
2 amplification and filtering circuitry receives electrical power from the handheld module, the  
3 electrical power being capacitively coupled to the first amplification and filtering circuitry.

1 30. The ECG module as defined by claim 24, wherein the signal  
2 processing circuitry of the ECG module includes first amplification and filtering circuitry for  
3 signals from leads and second amplification and filtering circuitry for processing signals from  
4 the first amplification and filtering circuitry for application to the handheld ultrasound  
5 diagnostic instrument, the first and second amplification and filtering circuitry being optically  
6 coupled.

1 31. The ultrasound instrument as defined by claim 30, wherein the first and  
2 second amplification and filtering circuitry are being magnetically coupled.

1 32. The ultrasound instrument as defined by claim 30, wherein the first and  
2 second amplification and filtering circuitry are being capacitively coupled.

1                    33.     In an electrocardiograph (ECG) module having first signal processing  
2     circuitry for processing ECG signals from a patient and second signal processing circuitry for  
3     further processing of the ECG signals for diagnostic use, a power supply circuit for providing  
4     electrical power from the system to the first signal processing circuitry comprising:

5                    a)       a serial inductive path for receiving a DC voltage and a shunt  
6     capacitive path and a shunt switch connecting the serial inductive path to a power ground;

7                    b)       a first coupling capacitor for coupling the serial inductive path to the  
8     first signal processing circuitry and a second coupling capacitor for coupling the power  
9     ground to the first signal processing circuitry; and

10                   c)       a rectifying circuit in the first signal processing circuitry including a  
11     forward polarity diode connecting the first coupling capacitor to a first terminal of a positive  
12     charge capacitor and a reverse polarity diode coupling the first coupling capacitor to a first  
13     terminal of a negative charge capacitor, and an isolated reference terminal connected to the  
14     second coupling capacitor and to a second terminal of the positive charge capacitor and to a  
15     second terminal of the negative charge capacitor whereby electrical power is coupled through  
16     the coupling capacitors to the charge capacitors at the frequency of the shunt switch.

1                    34.     The power supply circuit as defined by claim 33, wherein the  
2     electrocardiograph module is used with a handheld ultrasound diagnostic instrument and  
3     includes patient isolation from the system power supply which meets the requirements of  
4     ANSI/AAMI EC13 specification.

1                    35.     A power interface for coupling DC power from a non-isolated system  
2     to signal processing circuitry isolated from the system power supply comprising:

3                    chopping circuitry for chopping DC power supply voltage of the system;

4                    coupling capacitors for coupling power supply voltage to isolation circuitry;

5     and

6                    rectifying circuitry in the signal processing circuitry for receiving and  
7     rectifying the capacitively coupled chopped DC voltage.

1                    36.     The power interface as defined by claim 35, wherein the chopping  
2     circuitry comprises serially connected inductors connected to one coupling capacitor and a  
3     shunt capacitor and a shunt switch connecting a common terminal of the serially connected  
4     inductors to the power supply system ground and the second coupling capacitor.

1 37. A lightweight, handheld system for performing electrocardiography  
2 comprising:

3 a handheld ultrasound device weighing less than seven pounds having a  
4 transducer, a beamformer, an image processor and one or more digital signal processors for  
5 signal filtering, detection and mapping; and

6 a portable electrocardiogram monitor weighing less than three pounds and  
7 having at least three electrical leads for measuring electrical potential across a person's chest,  
8 a differential amplifier for amplifying the measured electrical potential, a plurality of signal  
9 filters and gain amplifiers, and a means for electronically isolating the measured signal from  
10 other electrical inputs and interferences.

1 38. The system of claim 37, wherein the plurality of signal amplifiers  
2 further comprise a bandpass filter, a highpass filter, and a lowpass notch filter.

1 39. A method of performing spectral Doppler analysis in a hand held  
2 ultrasound system comprising the steps of:

3 (a) analyzing the display data to restructure the original power frequency  
4 spectrum;

5 (b) performing a temporal smoothing on the frequency spectrum;

6 (c) determining the absolute value deviation for each frequency spectrum;

7 (d) determining the mean power per frequency spectrum;

8 (e) applying one of several fixed smoothing filters to each frequency  
9 column;

10 (f) finding the maximum value before the mean of each frequency  
11 spectrum;

12 (g) establishing a frequency spectrum threshold;

13 (h) employing a peak finding algorithm;

14 (i) applying a fixed width filter for temporal smoothing; and

15 (j) reversing the process of (a) to return the image data to the size  
16 appropriate for the system display.

1 40. The method of claim 39, wherein step (b) is omitted.

1 41. In a programmable diagnostic ultrasound instrument having stored  
2 software and data for operation control, a software security mechanism which restricts

3 modification of software or data including an algorithm which generates a keycode based on  
4 a unique system identifier which allows a person or agency to perform a system or data  
5 update.

1 42. The programmable diagnostic ultrasound instrument of claim 41,  
2 wherein the system or data update is performed through a detachable scanhead.

1 43. The programmable diagnostic ultrasound instrument of claim 41,  
2 wherein the software security mechanism is a signature generator.

1 44. The ultrasound instrument of claim 41, being a portable ultrasound  
2 instrument.

1 45. The ultrasound instrument of claim 41, being a hand held ultrasound  
2 instrument.

1 46. The ultrasound instrument of claim 41, weighing less than ten pounds  
2 (4.5 kg).

1 47. An ultrasound instrument having a software library and data for  
2 operational control stored on a persistent memory device, and having a means for securely  
3 enabling and disabling applications within the software library.

1 48. A programmable diagnostic ultrasound instrument having a plurality of  
2 diagnostic modes, wherein access to the diagnostic modes is controlled through a gate flag  
3 registry, the gate flag registry capable of modification through a verification procedure  
4 utilizing a secure means for extracting hidden bits from a keycode based on one or more  
5 unique system identifiers.

1 49. The programmable diagnostic ultrasound instrument of claim 48,  
2 wherein the verification procedure for extracting hidden bits from a keycode further  
3 comprises a compound algorithm including a signature generator, an encryption algorithm  
4 and a reversible logic operation, the compound algorithm being capable of verifying a  
5 keycode when operated in a decryption mode, and able to produce a verification data string  
6 having error detection bits, signature bits, and option bits.

1                    50.     The compound algorithm of claim 49, wherein more than one signature  
2 generator is used.

1                    51.     The compound algorithm of claim 49, wherein more than one  
2 encryption algorithm is used.

1                    52.     The programmable diagnostic ultrasound instrument of claim 49,  
2 wherein the compound algorithm further comprises a plurality of algorithms dependent upon  
3 each other for input values of various stages of their logic, a first algorithm producing a first  
4 bit string used by the second algorithm to produce a second bit string, the second bit string  
5 being required by the first algorithm to produce a new bit string  $n_{x+1}$  needed by said second  
6 algorithm to produce a new bit string  $n_{x+2}$ , wherein the logic strings ( $n_{x+y}$ ) are used by said  
7 first algorithm and said second algorithm until the plurality of algorithms complete all logic  
8 operations and produce a final bit string  $n_{xf}$ .

1                    53.     The programmable diagnostic ultrasound instrument of claim 52,  
2 wherein the logic of the dependent algorithms may be executed in reverse to produce any one  
3 of the input values produced by the other algorithm, or any one of the starting input values.

1                    54.     The programmable diagnostic ultrasound instrument of claim 52,  
2 wherein at least one of the algorithms is a data encryption algorithm.

1                    55.     The compound algorithm of claim 49, wherein the reversible logic  
2 operation is any logic operation capable of combining the bit strings of the signature  
3 generator and the encryption algorithm to produce a keycode when run in encryption mode,  
4 and produce the necessary verification data string when run in decryption mode.

1                    56.     The programmable diagnostic ultrasound instrument of claim 48,  
2 wherein the verification procedure is executed through an application specific integrated  
3 circuit (ASIC) that draws instrument specific information from either a software data  
4 structure, or a hardware data registry.

1                    57.     The ultrasound instrument of claim 48, being a portable ultrasound  
2 instrument.

1 58. The ultrasound instrument of claim 48, being a hand held ultrasound  
2 instrument.

1 59. The ultrasound instrument of claim 48, weighing less than ten pounds  
2 (4.5 kg).

1 60. In a programmable diagnostic ultrasound instrument having stored  
2 software and data for operation control, a software security mechanism which restricts  
3 modification of software or data utilizing a 64-bit mixing algorithm and a bit-wise signature  
4 generator within an architecture using a X-OR logic to perform reversible encryption and  
5 decryption operations, thereby allowing a user to change software or data using a short  
6 sequence of numbers while providing the security of a large bit string verification scheme  
7 enabling signature verification, error correction and licensing verification.

1 61. The programmable diagnostic ultrasound instrument of claim 60,  
2 wherein said instrument is a hand held device.

1 62. The programmable diagnostic ultrasound instrument of claim 60,  
2 weighing less than ten pounds (4.5 kg).

1 63. A system for the tracking diagnostic modes in one or more  
2 programmable diagnostic ultrasound instrument(s) comprising:

3 a) a general purpose computer having a means for generating a unique  
4 keycode for each programmable diagnostic ultrasound instrument, the keycode having  
5 encrypted error detection bits, signature bits and options bits for enabling diagnostic modes in  
6 a particular instrument;

7 b) at least one programmable diagnostic ultrasound instrument having a  
8 plurality of diagnostic modes that can be enabled or disabled upon successful verification of  
9 the keycode, the verification procedure utilizing a secure means for extracting hidden bits  
10 used to modify a gate flag registry from the keycode; and

11 c) a data structure for centrally recording and tracking diagnostic modes  
12 of each diagnostic ultrasound instrument.

1 64. A system as described in claim 63, wherein each programmable  
2 diagnostic ultrasound instrument links into a central database and receives a verification code

3 from the central database before any changes in the software libraries of the diagnostic  
4 ultrasound devices may be implemented.

1 65. The system as described in claim 64, wherein a person links into the  
2 central database by calling a database controller to receive a verification code via a telephone  
3 or fax machine.

1 66. The system of claim 64, wherein the verification code is a keycode  
2 which must be verified by the diagnostic ultrasound device through a logic process utilizing  
3 unique system identifiers, said unique system identifiers being unique for each said  
4 diagnostic ultrasound device.

1 67. A method of upgrading the functional software of a programmable  
2 diagnostic ultrasound instrument comprising the steps of:

3 (a) generating a keycode generation algorithm comprising at least one  
4 encryption algorithm, at least one signature generator, and a reversible logic operation for  
5 mixing a bit string produced by said encryption algorithm and a bit string produce by said  
6 signature generator;

7 (b) generating a keycode using the keycode generation algorithm, said  
8 keycode utilizing data specific to a programmable diagnostic ultrasound instrument and data  
9 relating to a desired software upgrade;

10 (c) inputting the keycode obtained from the step (b) into the  
11 programmable diagnostic ultrasound instrument; and

12 (d) verifying the keycode generated by step (b) in the programmable  
13 diagnostic ultrasound instrument, using a reversing algorithm of step (a) to compare and  
14 verify the signature bits, error detection bits and option bits.

1 68. The method of claim 67, wherein step (b) further comprises the steps  
2 of:

3 (b1) inputting instrument specific information into a keycode encryption  
4 algorithm;

5 (b2) providing one or more secret constants to the keycode encryption  
6 algorithm;

7 (b3) executing the operation of the encryption algorithm;

8 (b4) choosing a series of options to enable, each option coding for a desired  
9 software upgrade, in the programmable diagnostic ultrasound instrument and entering the  
10 series of options into a signature generator algorithm;

11 (b5) generating a first bit string in the signature generator having an equal  
12 length to a second bit string produced by the encryption algorithm;

13 (b6) executing a X-OR function on the first and second bit strings to  
14 produce a third bit string;

15 (b7) converting the third bit string to a decimal string; and

16 (b8) producing a keycode.

1 69. The method of claim 67, wherein step (c) further comprises the step of:

2 (c1) loading a new software application into the programmable diagnostic  
3 ultrasound instrument; and

4 (c2) enabling the new software application by inputting the keycode  
5 obtained from the vendor, into the programmable diagnostic ultrasound instrument.

1 70. The method of claim 67, wherein step (d) further comprises the steps  
2 of;

3 (d1) converting the license string into the X-or bit string;

4 (d2) generating a second bit string by running the encryption algorithm  
5 internally within the programmable diagnostic ultrasound instrument;

6 (d3) reversing the X-or logic on the X-or bit string and the second bit string  
7 to produce a first bit string;

8 (d4) isolating the signature bits, option bits and error detection bits of the  
9 first bit string;

10 (d5) comparing the signature bits, the option bits and the error detection bits  
11 generated by the reverse X-or first bit string to the internally generated first bit string; and

12 (d6) enabling the necessary options programmed through the option bits.

1 71. The method of claim 67, further comprising the step of recording in a  
2 database the particular options that are enabled on a particular programmable diagnostic  
3 ultrasound instrument.

1 72. The method of claim 67, wherein the programmable diagnostic  
2 ultrasound device is portable.

1                    73.     The method of claim 67, wherein the programmable diagnostic  
2     ultrasound device is hand held.

1                    74.     The method of claim 67, wherein the programmable diagnostic  
2     ultrasound device is less than ten pounds (4.5 kg).

1                    75.     The method of claim 67, wherein the logic is executed within an  
2     application specific integrated circuit (ASIC) using one or more fixed registries for input  
3     values.

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